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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,771	08/04/2003	Eric Vivier	INN-113TD2	6493
23557	7590	03/14/2006	EXAMINER	
SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950			SISSON, BRADLEY L	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 03/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/633,771	Applicant(s) VIVIER ET AL.	
	Examiner Bradley L. Sisson	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-66 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 24-66 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Vacation of Prior Office Action

1. The non-final Office action mailed 26 September 2005 is hereby vacated as it did not take into consideration the preliminary amendment filed 04 August 2003, whereby claims 1-23 were canceled and new claims 24-66 were added.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 24, 26-34, 37-45, and 66, drawn to a method of identifying repertoire of NKR inhibitory receptors in a subject, classified in class 435, subclass 6.
- II. Claims 25-32, 35-45, drawn to a method of identifying repertoire of NKR activatory immunoreceptors within a subject, classified in class 435, subclass 6.
- III. Claims 46 and 47, drawn to a kit, classified in class 536, subclass 24.33.

3. The inventions are distinct, each from the other because of the following reasons:

4. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to different methods that are comprised of different method steps and which result in different end products.

5. Inventions III and I-II are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP

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§ 806.05(h). In the instant case the product as claimed can be used in a materially different process of using that product, such as the methods of Group I or the method of Group II.

6. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, and because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

7. This application contains claims directed to the following patentably distinct species: In the event that applicant elects the invention of Group I, applicant is required to elect one of the following species for examination:

- a. Claims 33 and 57, method used to document genotypic repertoire of KIR immunoreceptors; and claims 34 and 58, method used to document the expression repertoire of KIR immunoreceptors.
- b. Claims 40-64, method used to predict or monitor acceptance or rejection, by a subject, of cells, tissue, or organ.
- c. Claims 41 and 65, method used to predict or to monitor safety or pathogenicity (GVH), for a subject, of a graft or transplant, of cells, tissue, or organ.
- d. Claims 42 and 66, method used to predict or to monitor for a subject of a GVL-type effect on the part of cells, tissue or organ, which are genetically different.
- e. Claim 43, drawn to use of method to determine the state of activation of NK and/or T cells within a subject.
- f. Claim 44, drawn to a method of predicting or monitoring the state of resistance of a subject to (i) infection, (ii) autoimmune disease, or (iii) development of malignant cells.

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8. The species are independent or distinct because the species are all drawn to different methods that result in different end products.

9. In the event that applicant elects the invention of Group II, applicant is required to elect one of the following species for examination:

- a. Claims 35 and 59, method used to document genotypic repertoire of KAR immunoreceptors; and claims 36 and 60, method used to document the expression repertoire of KAR immunoreceptors.
- b. Claims 40-64, method used to predict or monitor acceptance or rejection, by a subject, of cells, tissue, or organ.
- c. Claims 41 and 65, method used to predict or to monitor safety or pathogenicity (GVH), for a subject, of a graft or transplant, of cells, tissue, or organ.
- d. Claims 42 and 66, method used to predict or to monitor for a subject of a GVL-type effect on the part of cells, tissue or organ, which are genetically different.
- e. Claim 43, drawn to use of method to determine the state of activation of NK and/or T cells within a subject.
- f. Claim 44, drawn to a method of predicting or monitoring the state of resistance of a subject to (i) infection, (ii) autoimmune disease, or (iii) development of malignant cells.

10. The species are independent or distinct because the species are all drawn to different methods that result in different end products.

11. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be

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allowable. Currently, claims 24, 26-32, 37-39, 48, 50-56, and 61-63 generic with respect to Group I; and claims 25-32, 37-39, 49-56, and 61-63 are generic with respect to Group II.

12. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

13. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

14. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

15. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

16. Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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17. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

19. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

20. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
07 March 2006